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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/830,195

04/22/2004

Marcia Buiser

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EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/830,195

Applicant(s)

BUISER ET AL.

Examiner

Leah Schlientz

Art Unit

1618

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 June 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-17, 19-31 and 49-59 is/are pending in the application.
- 4a) Of the above claim(s) 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-15, 17, 19-31 and 49-59 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 6/5/2007, in reply to the Office Action mailed 4/4/2007, is acknowledged and has been entered. Claims 1, 6 – 17, 19, 20 and 25 have been amended. Claims 5, 18 and 32 – 48 have been cancelled. New claims 49 – 59 have been added. Claim 16 is withdrawn from consideration as being drawn to a non-elected species. Claims 1 – 4, 6 – 17, 19 – 31 and 49 – 59 are pending and are examined herein on the merits for patentability.

Response to Arguments

Applicant's arguments, filed 6/5/2007 have been fully considered. All rejections not reiterated herein have been withdrawn as having been overcome by amendment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 8, 9, 15 – 17, 19 – 23, 25, 26 and 28 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), for reasons set forth in the Office Action mailed 4/4/2007.

Claims 1 – 4, 6 – 15, 17, 19 – 26 and 28 – 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi *et al.*, for reasons set forth in the Office Action mailed 4/4/2007.

Applicant argues on page 8 – 9 of the Response that Jacobsen does not disclose how to make a particle chain, and that Greene's methods involve putting a polymer member in a tubular holder followed by coaxially skewering the polymer membrane with the filamentous carrier, or disposing a filamentous carrier in a mold followed by transferring polymer under pressure into the mold. Applicant argues that Smith makes his polymer by spraying polymer solution into a precipitation bath, and thus one skilled in the art would not be motivated to try to combine the references.

This is non-persuasive because Jacobsen teaches that the fixed beads may be integrally formed on the material of the filament (page 4, lines 23 – 24 and claim 25). The entire thrust of the Jacobsen patent is focused on interconnected miniature beads, and thus it is interpreted, in the absence of evidence to the contrary, that one of ordinary skill in the art must be capable of preparing such a linear sequence of interconnected

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beads which are integrally formed on the material of the filament. The Greene and Mazzocchi references are included to show that the claimed linker width / length / aspect ratios are known in the art to be variable for preparation of linked beads on a carrier in embolic devices. Regarding the Smith reference, Smith teaches additional synthetic methods in addition to those cited, see also Smith column 5.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 – 4, 6 – 17, 19 – 20, 23 – 31, 49 – 54 and 59 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for polymeric particles having an interior region with pores having a mean size, and a surface region with pores having a mean size, wherein the mean size of the pores of the interior region is greater than the mean size of the interior region of the particle, does not reasonably provide enablement for any and all “particles” or any and all “materials.” The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546

(BdApls 1986) at 547 the court recited eight factors:

- 1) the quantity of experimentation necessary,
- 2) the amount of direction or guidance provided,
- 3) the presence or absence of working examples,
- 4) the nature of the invention,
- 5) the state of the prior art,
- 6) the relative skill of those in the art,
- 7) the predictability of the art, and
- 8) the breadth of the claims.

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth herein below.

The nature of the invention and the state of the prior art

The invention is drawn to a particle chain having at least two connected particles and a link that connects the at least two connected particles, wherein the link is integrally formed with at least one of the at least two connected particles. At least one of the particles have an interior region with pores having a mean size, and a surface region with pores having a mean size, wherein the mean size of the pores of the interior region is greater than the mean size of the interior region of the particle. Within the prior art, particles of a wide variety of materials, such as polymeric particles, metal particles, drug particles, etc. are known.

The breadth of the claims, the relative skill of those in the art, and the predictability of the art

The claims are very broad, and are inclusive of any and all "particles" or any and all particles comprising a "material," as claimed in claims 1 and claim 54. However, one

of ordinary skill in the art would not be able to be aware of how to prepare particles of any and all materials having the claimed properties.

The amount of direction provided, the presence of working examples, and the quantity of experimentation necessary

The specification provides direction only for preparing polymeric particles having the claimed pore density ranges. See for example, paragraphs 0134 – 0161, wherein a drop generator, a gelling vessel, a reactor vessel, etc. deliver and process solutions of base polymer and a gelling precursor in the production of polymeric particles. It would require a great deal of undue experimentation to adapt the disclosed method of polymeric particle formation in order to identify methods of preparing particles of any and all materials having the claimed properties. Furthermore, the disclosure of a method of providing particles which are “integrally formed” with a link, as required by claim 1, appears to be that of paragraph 0149, which is drawn to polymeric solutions. It would require undue burden for one of ordinary skill in the art to extend these practices to obtain materials and links of other materials (i.e. metals, etc.). Applicant's limited disclosure of polymeric particles does not provide adequate support for claiming any and all “particles” or “materials.”

Claims 15, 17, 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed,

had possession of the claimed invention. The claims have been amended to recite that a link connects at least two connected particles, wherein the link is integrally formed with at least one of the at least two connected particles. Applicant's disclosure of a method of providing particles which are "integrally formed" with a link, as required by claim 1, appears in paragraph 0149, which are drawn to polymeric solutions. It does not appear that applicant envisaged a link that was integrally formed with at least one of at least two particles via a metal linker, or a grafted linker, which are described as being prepared by different processes (e.g. threading, as in metal, or grafting) (paragraph 0148).

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 4, 6 – 17, 19 – 31, and 49 – 53 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a particle chain having at least two connected particles and a link that connects the at least two particles, wherein the link is integrally formed with at least one of the at least two connected particles. It is unclear what is to be encompassed by the term "integrally formed." While an example of integrally formed particles connected via a link which are made by a specific process is provided in paragraph 0149, it is unknown what other types of connections may be represented by integrally formed links and particles. The term does not appear to be a term of art. The metes and bounds of

the claim cannot be distinctly ascertained from such a limitation, because there is no clear definition of what is to be represented by a link and a particle which are integrally formed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 2, 8, 9, 15 – 17, 19 – 23, 25, 26, 28 – 31 and 49 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), for reasons set forth in the Office Action mailed 4/4/2007.

Regarding newly added claims 49 – 53, Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding newly added claim 56, Greene teaches a particularly desirable porous polymeric material to be PVA (column 11, lines 55+).

Claims 1 – 4, 6 – 15, 17, 19 – 26, 28 – 31 and 49 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) and Greene *et al.* (US 2002/0177855), in view of Smith *et al.* (US 5,888,930), in further view of Mazzocchi *et al.*, for reasons set forth in the Office Action mailed 4/4/2007.

Regarding newly added claims 49 – 53, Jacobsen teaches that the carriers may be any desired length, and thus it would have been obvious to one of ordinary skill in the art to selectively prepare links within the claimed ranges. Regarding newly added claim 56, Greene teaches a particularly desirable porous polymeric material to be PVA (column 11, lines 55+).

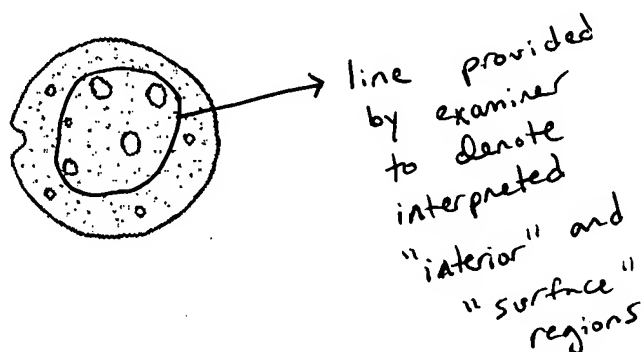
Claims 1 – 7, 15, 17, 19, 21, 22, 25 – 31 and 49 – 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobsen *et al.* (US 6,530,934) in view of Mangin (WO 01/66016).

Jacobsen discloses an embolic device comprised of a linear sequence of flexibly interconnected miniature beads. The device generally comprises a flexible elongated filament having a linear sequence of beads disposed thereon. The beads may be fixedly connected to the filament. The beads may be integrally formed on the material of the filament (column 4, line 24). The string of beads may be configured to the exact length needed. The beads may be porous (abstract). The embolic device is used to occlude blood flow and/or initiate blood clotting upon introduction to the body via a catheter (column 1, lines 14 – 25). The string of beads includes a filament (i.e. a link) and beads. The beads have diameters from 0.002 inches to 0.0018 inches, and may be

made of a variety of materials, including polymers, radioopaque polymers, metals. The string of beads may be comprised of beads of several different materials (column 4, lines 25 – 40). The filament can be a multi or monofilament polymer (column 5, line 21). The string of beads may be configured as a drug delivery device, wherein the beads are porous and contain a medicament for controlled release into the interior of the body (column 2, lines 44 – 47).

Jacobsen does not specifically recite that the polymer is polyvinyl alcohol, and does not specifically recite that the porous beads have interior and surface regions wherein the mean size of pores of the interior region is greater than the mean size of pores of the surface region.

Mangin discloses embolic particles suitable for effectuating embolization or occlusion of a vessel or duct (abstract). Such particles have one or more voids on the surface and present within the particles. The particles may be a variety of sizes (see page 7, lines 18 – 35). The voids may be filled with biologically active agents or drugs page 9, line 23 – 26. The embolic particles are preferably made of PVA (page 4, line 34). The particles appear to be capable of having larger pore sizes, on average, in an “interior region” of the particle as opposed to a “surface region.” See Figure B. The examiner arbitrarily defines a “surface region” and an “interior region” as shown below:



It would have been obvious to one of ordinary skill in the art at the time of the instant invention to apply porous PVA particles, such as those taught by Mangin, in an interconnected form, as taught in the device of Jacobsen because both the porous particles of Mangin and the interconnected porous beads of Jacobsen are used for embolization. One would have been motivated to do so, and would have had a reasonable expectation of success in doing so, because Jacobsen specifically teaches that hydrophilic particles which are used for occluding blood flow tend to become dislodged from the target site and migrate within the body potentially causing trauma or unwanted thrombosis, and that providing a device comprising a linear sequence of interconnected miniature beads is superior to individual particles because the device is less susceptible to migration within the body (column 1 – 2).

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

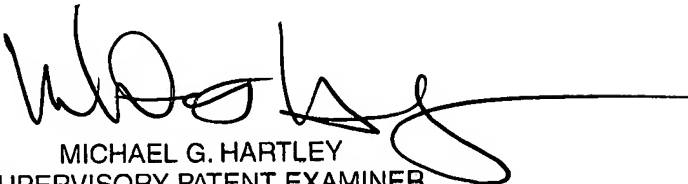
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LHS


MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER